

light chain, which is able to bind to GPIIb/IIIa (of a human antibody or a fragment thereof),

and wherein the light chain comprises a CDR3 region, selected from:

(a) a nucleotide sequence which encodes the amino acid sequence:

A T W D D G L N G P V (SEQ ID NO:37),

(b) a nucleotide sequence which encodes the amino acid sequence

A A W D D S L N G W V (SEQ ID NO:38), and

(c) a nucleotide sequence which encodes an amino acid sequence having an homology
of at least 80% with an amino acid sequence from (a) or (b).--

—36. A composition comprising an antibody or antibody fragment according to claim 35

in combination with adjuvants, additives or excipients --

REMARKS

In the Office Action dated November 12, 2002, claims 13-16, 19 and 26-27, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks.

The disclosure was objected to as lacking a reference to the PCT application. A reference to PCT/EP98/03397 has been inserted at the beginning of the application. The disclosure was also objected to regarding the trademark "ReoPro" on page 14. Applicants respectfully point out that this trademark is capitalized, includes the appropriate trademark symbol "®" and is accompanied by generic terminology (i.e. fragments of murine monoclonal

antibodies, page 14, lines 16-20). In view of this, applicants do not believe that any correction is necessary.

Claims 13-16, 19 and 26-27 were objected to as lacking sequence ID numbers in claims 13 and 16. Claims 13-16, 19 and 26-27 have been canceled and new claims added to the application which include sequence ID numbers.

Claims 13-15 and 26 were rejected under 35 USC §101 as directed to nonstatutory subject matter. Claims 13-15 and 26 have been canceled and the new claims added to the application recite an “isolated antibody or antibody fragment”.

Claims 26 and 27 were rejected under 35 USC §112, first paragraph. Claims 26 and 27 have been canceled and the language which was objected to is not included in the new claims.

Claims 13-16, 19, and 26-27 were rejected under 35 USC §112, second paragraph, as indefinite due to the term “derivative”. Claims 13-16, 19, and 26-27 have been canceled and new claims added to the application which do not recite “derivative”

Claims 26-27 were rejected under 35 USC §112, second paragraph, as indefinite. Claims 26-27 have been canceled and new claims added to the application which do not include the language found indefinite in part (c).

Claims 14 and 15 rejected under 35 USC §112, second paragraph, as indefinite. Claims 14 and 15 have been canceled and the new claims added to the application which use the language “further comprising”.

Claim 16 was rejected under 35 USC §112, second paragraph, as indefinite regarding the language “coupled to a labeling group”. Claim 16 has been canceled and the new claims added to the application indicate that the labeling group is a detectable labeling group.

Claims 13-16, 19 and 26-27 were rejected under 35 USC §112, second paragraph, as indefinite regarding the language "comprises a CDR3 region". Claims 13-16, 19 and 26-27 have been canceled and new claims added to the application which clarify whether the CDR3 region is from a heavy or a light chain.

Claims 19 and 27 were rejected under 35 USC §112, second paragraph, as indefinite regarding "the active component". Claims 19 and 27 have been canceled and new claims added to the application which do not include the language found indefinite.

Claims 13-16, 19 and 26-27 were rejected under 35 USC §112, first paragraph, as lacking enablement. Applicants respectfully point out that the CDR3 region of the heavy chain of the antibody is the only region which is critical for bonding to an antigen. The presence of other sequences (e.g. the CDR2 and/or CDR1 region from the heavy chain or the CDR3, CDR2 and/or CDR1 regions from the light chain) can improve the bond but the heavy chain CDR3 region alone is sufficient for bonding. In addition, specific variations in the amino acid sequence of a CDR3 region have been found to be tolerable. Applicants respectfully contend that the newly added claims are enabled and request that this rejection be withdrawn.

Claims 19 and 27 were rejected under 35 USC §112, first paragraph, as lacking enablement regarding in vivo uses. Applicants respectfully point out that the composition can be used as a diagnostic agent or a therapeutic agent as discussed on page 13 of the present specification. Since the antibodies have been shown to retain the desired binding, applicants contend that one skilled in the art would be able to use the claimed composition for the purposes disclosed in the present application and request that this rejection be withdrawn.

Claims 13-16, 19, 26-27 were rejected under 35 USC 102(b) as anticipated by Berchtold. Applicants respectfully point out that Berchtold discloses polyclonal antiseraums

consisting of a plurality of different antibody species. Berchtold does not suggest or disclose the isolation of a specific monoclonal antibody species or the sequences of the antibodies according to the present invention. In addition, the human antibodies in the present invention were obtained from a healthy human donor while the antibodies in Berchtold (and Nugent) were obtained from diseased patients (i.e. AITP patients). Thus, the antigen binding sequences according to the present invention were derived from the genome of a healthy individual and are less likely to have side effects during therapeutic administration. In view of the fact that Berchtold does not disclose an isolated antibody or antibody fragment with the specified CDR3 region which was derived from a healthy patient, applicants request that this rejection be withdrawn.

Claims 13-16, 19, and 26-27 were rejected under 35 USC §102(b) as anticipated by Nugent. Applicants respectfully point out that CDR3 regions in human monoclonal antibodies exhibit considerable variability and therefore it is extremely unlikely that the antibody 5E5 disclosed by Nugent would have the same CDR3 sequences as the antibody of the present invention. The diversity of autoantibodies against GpIIb/IIIa is known in the art as shown by Kunicki et al., cited in the office action dated November 10, 2001, and WO 98/55146. In addition, as discussed above, the human antibodies in the present invention were obtained from a healthy human donor while the antibodies in Nugent were obtained from diseased patients (i.e. AITP patients), further decreasing the possibility that Nugent isolated antibodies with CDR3 regions as recited in the present claims. In view of the fact that Nugent does not disclose an isolated antibody or antibody fragment with the specified CDR3 region which was derived from a healthy patient and thus is unlikely to have isolated antibodies with the recited CDR3 regions, applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 30-36 are in condition for allowance.

If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By



Monica Chin Kitts
Attorney for Applicants
Registration No. 36,105
ROTHWELL, FIGG, ERNST & MANBECK, p.c.
Suite 800, 1425 K Street, N.W.
Washington, D.C. 20005
Telephone: (202)783-6040